



Dennis
McNeilly/DC/USEPA/US
03/29/2007 08:40 AM

To Bryant Crowe/DC/USEPA/US@EPA
cc Tony Kish/DC/USEPA/US@EPA, Cynthia
Giles-Parker/DC/USEPA/US@EPA, Richard
Loranger/DC/USEPA/US@EPA, Christina
bcc
Subject Sodium chlorite (Residue Chemistry Waivers) ----- Biox Plus


History:  This message has been replied to.

Bryant

HED has already provided you with the text for rejecting the Field Volatility Waiver request for worker/bystander exposure (thanks to Billy Smith). Here is our assessment/recommendation concerning the Residue Chemistry waivers. We recommend accepting the plant metabolism waiver request but not the Magnitude of the Residue (MOR) waiver request. In addition, our recommendation on the analytical method waiver request depends on certain conditions and the outcome of the residue studies (residues <0.01 ppm?) as specified in the MOR waiver section. Attached is the Word version that you could use in RD's 75-day letter to the registrant. Sorry for the delay, but we wanted you to be able to address all the issues in one letter.

If this attachment is not clear, give me a call.

You might want to send a draft of the letter to us before it goes out. Your call.

Dennis



Waiver Request for Magnitude of the Residue.doc

Waiver Request for Magnitude of the Residue Data

HED recommends against granting a waiver request for magnitude of the residue for sodium chlorite use on wheat, oats and barley. We cite the submitted study: Han, Y.; Selby, T.L.; Schultze, K.K.; Nelson, P.E.; Linton, R.H. 2004.

Decontamination of Strawberries Using Batch and Continuous Chlorine Dioxide Gas Treatments. *Journal of Food Protection*. 67:2450-2455. This study was submitted to support the waiver request. It evaluates efficacy and is not a residue study; however, limited information was provided on residues of chlorine dioxide and chlorite on strawberries after treatment with various concentrations and treatment time. Strawberries were treated with 3 mg/liter chlorine dioxide for 10 minutes and then maintained in storage for one week at 4°C. Residues of chlorine dioxide and chlorite immediately after treatment were 0.19 ± 0.33 ppm and 1.17 ± 2.02 ppm. One week after storage no chlorine dioxide residues were detected (LOD not provided) and chlorite residue levels reported as CL_2 equivalents were 0.07 ± 0.12 ppm.

In addition, the Agency (AD) asked the States of Idaho and Washington to collect analytical data on the residues on the chlorine dioxide treated post-harvest potatoes (AD Memo by Tim McMahon, and A. Najim Shamim, March, 1998). Chlorine dioxide, in the form of a spray, is applied in a mist and fogger with an application rate of 200-400 ppm for the post-harvest treatment of potatoes in the storage area before they are sent out for retail market (EPA Reg. No. 9804-5). A six month residue monitoring study from chlorine dioxide treatment on stored potatoes (February through July 1999) was submitted in August/September, 1999 by Analytical Sciences Laboratory, a contracting lab. Forty-two samples (duplicate) were analyzed: 1) All 42 samples showed chlorite to be non-detectable (at the practical quantitation limit of 0.1 ppm); and 2) 39/42 samples showed the presence of chlorate below the quantitation limit of 0.1 ppm and three samples showed the chlorate level between 0.97 and 1.1 ppm. Both chlorate and chlorite are considered the breakdown products of chlorine dioxide.

While these studies do indicate low residue levels, they do indicate the potential for finite residues of chlorite and chlorate. Even low residue levels on raw agricultural commodities (especially wheat) with significant consumption could pose a chronic risk. In addition, these studies were conducted using analytical methods with quantitation limits of 0.1 ppm, rather than at 0.01 ppm which HED normally prefers as the level below which residues are considered as "no detected residues." HED recommends that residue trials be conducted and data submitted for the analytes: chlorate, chlorite and chlorine dioxide. Preliminary calculations (using DEEM-FCID) indicate that an analytical detection limit of 0.01 ppm is needed for wheat grain if the petitioner is interested in pursuing the Threshold of Regulation (TOR) process in conjunction with this use.

Waiver Request for Analytical Enforcement Method.

HED recommends against granting a waiver request. An analytical method would be needed to conduct the magnitude of the residue studies cited above. Unless the TOR

policy is found to be applicable, the method would also need to be suitable for enforcement purposes.